REMARKS

Applicants have amended claim 1. No new matter has been added to the claims by way of this amendment. Claims 1-24 are now pending in this application.

Restriction Requirement

The Office required restriction under 35 U.S.C. § 121 between:

Group I, claims 1-21, drawn to a stabilized liquid preparation, classified in class 435, subclass183;

Group II, claims 22 and 23, drawn to a method of treating thromboembolic disorders, classified in class 424, subclass various;

Group III, claim 24, drawn to a method of treating disorders caused by fibrin-containing thrombi, classified in class 514, subclass various.

Applicants elect to prosecute Group I, claims 1-21, drawn to a stabilized liquid preparation, with traverse.

Applicants traverse on the ground that the Office has failed to establish that it would be unduly burdensome to search the methods of Group II and Group III once the stabilized liquid preparation employed in these methods have been searched. *See* M.P.E.P. § 803. Accordingly, Applicants respectfully request the restriction to be withdrawn.

The Office also required the following election of species.

The Office required an election of a species of "the different compounds in part (b) of claim 1." Office Action at page 3. Applicants hereby elect, with traverse, the tranexamic acid compound in part (b) of claim 1.

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Applicants traverse the species restriction on the ground that the claims do not define an unreasonable number of stabilizing agents. *See* 37 C.F.R. § 1.141. Moreover, it would be unreasonable to require Applicants to file many separate applications, one for each possible stabilizing agent. Applicants respectfully request, should this election requirement be maintained, that the scope of the examination be broadened to include a reasonable number of species. *See* 37 C.F.R. § 1.141(a).

A species must also be elected from "the different detergents used in the composition." Office Action at page 3. Applicants hereby elect, with traverse, non-ionic detergents.

Applicants traverse the species restriction on the ground that the claims do not define an unreasonable number of detergents. *See* 37 C.F.R. § 1.141. Moreover, it would be unreasonable to require Applicants to file many separate applications, one for each possible detergent. Applicants respectfully request, should this election requirement be maintained, that the scope of the examination be broadened to include a reasonable number of species, at least including ionic detergents. *See* 37 C.F.R. § 1.141(a).

applicant can then argue on the record that the obvious variants over each other

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 1-21 under 35 U.S.C. § 112, second paragraph, stating that "(c)laim 1 is confusing since it is not clear how a pH range can be considered to be a separate ingredient in the composition." Office Action at page 5. Applicants respectfully traverse. However, merely to expedite prosecution, Applicants

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have amended claim 1. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Rejections under 35 U.S.C. § 102(b)

The Office rejected claims 1, 6, 7, 20, and 21 under 35 U.S.C. § 102(b), as being anticipated by Sato et al. or Suganuma et al. Further, the Office asserted that the "references each teach that tranexamic acid can be used with a protease at a pH between 2-8." Office Action at page 5.

As set forth in M.P.E.P. § 2131, "[t]o anticipate a claim, the reference must teach every element of the claim." Further, "[t]he identical invention must be shown in as complete detail as is contained in the claim." The Applicants respectfully submit that the Office has not established anticipation, because neither Sato et al. nor Suganuma et al. teach a protease or proenzyme that activates blood coagulation factor VII. Applicants specifically claim that the protease or its proenzyme are only those that activate blood coagulation factor VII. *See* Claim 1. Neither Sato et al. nor Suganuma et al. disclose the claimed protease or proenzyme. Each reference merely states that a general class of "proteases" may be included as an ingredient of the composition. (Sato; col. 3, line 12; Suganuma; col. 2, line 64.) Because Sato et al. and Suganuma et al. fail to disclose Applicants' claimed protease and proenzyme, the references fail to anticipate claims 1, 6, 7, 20 and 21. Therefore, Applicants respectfully request the Office to withdraw this rejection.

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Rejections under 35 U.S.C. § 103(a)

The Office rejected claims 1-21 under 35 U.S.C. § 103(a), as being obvious over Sato et al. or Suganuma et al. in view of Pader, Ritchey et al., and Hoppe et al. Office Action at page 6. Further, the Examiner asserted that "it would have been well within the purview of the skilled artisan to add the ingredients together in order to form a single composition since they are all known individually to be used in a *toothpaste*." *Id.* (emphasis added). Applicants respectfully traverse this rejection.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) all claim limitations must be taught or suggested, (2) there must be some suggestion or motivation to modify the references or combine reference teachings, and (3) there must be a reasonable expectation of success. M.P.E.P. § 2143.03.

Applicants respectfully submit that the references provided by the Office do not teach or suggest all claim limitations. As stated above, Sato et al. and Suganuma et al. do not disclose Applicants' claimed protease and proenzyme. Pader et al., Hoppe et al. and Richey et al. do not cure this defect. Hoppe et al. and Richey et al. do not disclose or suggest any protease. Additionally, while Pader does disclose a protease (Pader et al., col. 1, line 17), the reference fails to specify a particular protease, stating only that the protease should be one that "could disrupt plaque matrix or other structural component of plaque." Pader et al., col. 3, lines 8-9. Thus, Pader et al. does not even remotely suggest Applicants' claimed protease. Taken together, the references fail to teach or suggest every element of the claimed invention. As such, the Office has failed to establish a *prima facie* case of obviousness and the rejection should be withdrawn.

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Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request the reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: April 10, 2003

By: _____
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Appendix to the Amendment

1. (AMENDED) A stabilized liquid preparation comprising:

a. a protease or its proenzyme, ~~which~~ wherein the protease or its proenzyme activates blood coagulation factor VII;

b. at least one compound selected from the group consisting of ornithine, diaminopimelic acid, agmatine, creatine, guanidinoacetic acid, acetylornithine, citrulline, argininosuccinic acid, tranexamic acid, and ε-aminocaproic acid or their salts and derivatives; and

c. wherein said preparation has a pH ~~between~~ from 2.0 ~~and~~ to 8.0.

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